

REMARKS

Claims 123, 126, 141, 149-152, and 159 are pending and stand rejected. Claim 123 has been amended to correct a typographical error. The claims have been amended as requested at the interview to clarify that the control unit is programmed in various ways as claimed. Reconsideration of the claims in view of the following remarks is respectfully requested.

Applicant thanks the Examiner and her supervisor for the in-person interview on January 19, 2012 with, Amir Tehrani and Applicant's representative, Esther Kepplinger. During the interview, proposed amendments were discussed in view of the cited references.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 123, 126, 141, 149-152, and 159 were rejected under 35 U.S.C. § 103(a) as allegedly being obvious in view of U.S. Patent No. 6,415,183 to Scheiner et al. ("Scheiner") in view of U.S. Pub. No. 2003/0153954 to Park et al. ("Park"). These rejections are respectfully traversed.

Claims 123 and 126, the sole pending independent claims, recite that the control unit of the claimed device is configured to deliver an electrical stimulation signal comprising a burst or series of pulses, to provide stimulation with each breath to incrementally adjust to the desired level and to stimulate to supplement a breath. These limitations recited in the claims are not shown by or made obvious by Scheiner or Park.

Scheiner shows an apparatus for treating respiratory ailments in which following detection of a problem, the electrode delivers an electrical stimulus to the phrenic nerve, "initiating a respiratory cycle" Col. 2, lines 2-6, and the phrenic nerve receives an electrical stimulus causing the diaphragm "to contract, causing a respiratory cycle to begin." Col. 3, lines 27-29. Thus, it is clear that Scheiner stimulates the phrenic nerve causing the diaphragm to contract and starts a respirator cycle. This does not teach or make obvious supplementing a breath as instantly claimed and Scheiner alone or in combination with Park do not make obvious these claims.

The Examiner points to Figure 4 and if the diaphragm does not respond, the voltage pulse level is increased. The Office action states that Fig. 4 shows that the stimulation pulse

is delivered at a predetermined frequency unless the input signal indicates that the minute ventilation is above a predetermined level (col. 7, lines 49-60). Then the examiner concludes that the stimulation parameter (voltage) is “incrementally adjusted until the breathing cycle is further adjusted to reach the desired level.” However, in Fig. 4 and the accompanying specification description, Scheiner states “If it is determined in block 404 that the diaphragm did not respond to the therapy, then the voltage pulse level is increased in block 405.” Adjusting the voltage to cause the diaphragm to contract is not incrementally adjusting the breathing. In such situation, the diaphragm responds to just the second stimulation, which cannot be considered as providing a stimulation with each breath to incrementally adjust. First, if the diaphragm does not respond, there is no breath and second, it is not an incremental adjustment but a single stimulation causing a new respiratory cycle. Such scenario does not meet or make obvious the claims reciting “provide stimulation with each breath to incrementally adjust.” The stimulation of Scheiner is not provided with each breath and does not “incrementally” adjust breathing. Also, it must be noted that Scheiner does not teach what to do when the minute ventilation is above the predetermined level.

Further, the claims require that the control unit of the device is programmed to deliver an electrical stimulation signal comprising a burst or a series of pulses. However, as in Scheiner stimulating once and if there is no response by the diaphragm, increasing the voltage and stimulating again would represent two electrical stimulation signals, not “an electrical stimulation signal” as claimed. This would not meet or make obvious the recitation of an electrical stimulation signal comprising a burst or series of pulses.

Also, Figures 10A and 10B in the original specification, for example, show various electrical stimulation signals delivered during inspiration so as to adjust the breathing cycle of the patient such as by increasing or decreasing the inspiration rate (time from trough to peak in curves of Fig. 10B) or tidal volume (area under curve in Fig. 10B). (*See also* original specification, pg. 24, ln. 16 – pg. 25, ln. 14.)

Scheiner and Park, alone or in combination, fail to disclose the delivery of an electrical stimulation signal specifically during the inspiration period of a patient’s breathing cycle. While Scheiner does disclose the delivery of an electrical stimulus when the need for therapy is detected (Scheiner, col. 2, lns. 2-9, col. 6, ln. 57-65, col. 7, lns. 15-28, lns. 46-60, col. 8, lns. 19-32, col. 10, lns. 18-30, Figs. 3-5, 7), Scheiner does not specifically disclose

during which part of a patient's breathing cycle (inspiration, exhalation, and rest) the electrical stimulation signal is delivered, much less disclose that the electrical stimulation signal is delivered during inspiration. Park suffers from the same deficiency as Scheiner. Park discloses the use of dynamic pacing of the heart to prevent sleep apnea, including the measurement of respiratory parameters. (Park, paras. 0021, 0040, 0041, 0053, 0054.) Park, however, does not disclose during which part of a patient's breathing cycle cardiac pacing pulses are delivered to the heart.

For at least the above reasons, Scheiner and Park, alone or in combination, do not disclose each and every element of claims 123 and 126. Therefore, *prima facie* obviousness of these claims cannot be established. Accordingly, Applicants respectfully request withdrawal of the obviousness rejections of independent claims 123 and 126 as well as claims 141, 149-152, and 159 which depend from either one or the other of the independent claims.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **RMXLNZ00100**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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